IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF TEXAS

FORT WORTH DIVISION

OUTSOURCING FACILITIES ASSOCIATION, ET AL	)	CASE NO. 4:24-CV-00953-P
	)	
	)	FORT WORTH, TEXAS
vs.	)	
	)	APRIL 24, 2025
UNITED STATES FOOD AND DRUG ADMINISTRATION, ET AL	)	1:50 P.M.

VOLUME 1
TRANSCRIPT OF MOTION FOR SUMMARY JUDGMENT
BEFORE THE HONORABLE MARK T. PITTMAN
UNITED STATES DISTRICT COURT JUDGE

A P P E A R A N C E S:

FOR THE PLAINTIFF:

ANDREW MICHAEL GROSSMAN
BakerHostetler, LLP
1050 Connecticut Avenue NW
Suite 1100
Washington, DC 20036
Telephone: 202.861.1697

TYLER GEOFFREY DOYLE
BakerHostetler, LLP
811 Main Street
Suite 1100
Houston, Texas 77002
Telephone: 713.646.1374

FOR THE DEFENDANT:
U.S. Food and Drug Administration

OLIVER MCDONALD
Consumer Protection Branch
450 Fifth Street NW
Room 6400-South
Washington, DC 20530
Telephone: 202.305.0168

JULIA LOVAS
Office of Chief Counsel
10903 New Hampshire Avenue
White Oak 31
Silver Spring, Maryland 20993

FOR THE INTERVENOR: Eli Lilly

ERIN E. MURPHY
Clement & Murphy, PLLC
706 Duke Street
Alexandria, Virginia 22314
Telephone: 202.742.8900

JAMES R P HILEMAN
Kirkland & Ellis, LLP
300 N. LaSalle Street
Chicago, Illinois 60654
Telephone: 312.862.7090

IAN BRINTON HATCH
Kirkland & Ellis
1601 Elm Street
Suite 2700
Dallas, Texas 75201
Telephone: 214.972.1781

COURT REPORTER:

MONICA WILLENBURG GUZMAN, CSR, RPR
501 W. 10th Street, Room 310
Fort Worth, Texas 76102
Telephone: 817.850.6681
E-Mail: mguzman.csr@yahoo.com

Proceedings reported by mechanical stenography, transcript produced by computer.

INDEX

P R O C E E D I N G S

(April 24, 2025, 1:50 p.m.)

THE COURT: We're here on the matter of Outsourcing Facilities Association, et al vs. the FDA. We have an intervenor party that's been added, Eli Lilly. We're here on parties' motions for summary judgment.

And I would like to begin by asking the counsel for plaintiffs to introduce themselves for the record.

MR. DOYLE: Thank you and good afternoon, Your Honor. Ty Doyle of BakerHostetler for plaintiffs, alongside my partner, Andrew Grossman.

THE COURT: Okay. And, Mr. Grossman, are you going to be handling most of the argument?

MR. GROSSMAN: Yes, Your Honor.

THE COURT: I'm assuming this is your area of expertise.

MR. GROSSMAN: In general, yes, Your Honor.

THE COURT: Okay. And who do I have for the FDA?

MR. MCDONALD: Your Honor, my name is Oliver McDonald from the Department of Justice for Federal defendants.

THE COURT: Okay.

MR. MCDONALD: With me at counsel table is Julie Lovas, from the Food and Drug Administration's Office of Chief Counsel.

THE COURT: All right.

And who do I have for Eli Lilly?

MR. HATCH: For Eli Lilly, it's Ian Hatch and James Hileman from Kirkland & Ellis, and we have Erin Murphy from Clement & Murphy as well.

THE COURT: Okay. Who -- who will be doing the argument or most of the argument for your side, Mr. Hatch?

MR. HATCH: Erin Murphy will be, Your Honor.

THE COURT: All right.

I do have some questions, but I want you-all to be able to make your presentation, so I'll try not to interrupt. And I think it's best if we hear from counsel for the plaintiff. And as I said, I'll be generous with my time, so don't worry about going over. We have some time that's been given back to us.

Mr. Grossman, I look forward to hearing from you.

MR. GROSSMAN: Thank you, Your Honor.

Good afternoon. Thank you for taking the time to hold the hearing today.

Tirzepatide went into shortage because of surging demand for the drug. And the theory for the FDA's action removing Tirzepatide from the shortage list, is that Eli Lilly increased its manufacturing capacity and caught up with the demand. But even Lilly's own presentation of data showed that the race was neck and neck, with supply [redacted]

[redacted]. That should have led the FDA to take a hard look at Lilly's presentation and decide whether the evidence satisfied the agency's standard for ending a shortage.

But that's not what the FDA did. Rather than reason through the problem and apply its own standard, it deferred to Lilly's presentation and Lilly's choices across the board.

Why did the FDA analyze a [redacted] of supply and demand data? Because that was the data that Lilly happened to submit to the agency.

Why did the FDA rely on supply numbers that, according to Lilly, don't reflect the actual supply available to fulfill customer demands? Because those were the numbers that Lilly gave to the agency.

Why did the FDA determine that Lilly could [redacted] Because Lilly said, without any support, that it could do so.

FDA's across-the-board deference to Lilly's choices require vac- -- vacatur of its delisting action for two reasons that I'd like to address this afternoon. The first is a lack of reasoned explanation for the agency's choices and its methodology. And the second is a lack of substantial evidence supporting the agency's determination. And if time allows, which it may well do so now, I'd like to also make a

few points regarding the notice and comment argument as well.

Beginning with the lack of reasoned explanation point, the agency's delisting action, the decision that it issued, doesn't apply any apparent methodology. The decision announces, up top, right on page 1, that the inquiry before the agency under the statute is whether demand exceeds supply over a particular period of time. That's on page 1; it's on page 3, when the agency begins its analysis.

So what you would expect to see in the decision, is that the agency would identify a period of time, and that it would make findings for supply and demand over that period of time. Needless to say, the decision does not carry out that methodology. Instead, what it does is it proceeds to recite each category of data from Eli -- that Eli Lilly has given it, and then it states that the data, and I quote, "supports our conclusion."

So what metric or criteria is the decision actually applying in this analysis? The decision never actually says, and it certainly isn't obvious on the face of the decision. It's effectively applying an I-know-it-when-I-see-it type of standard, but that's not a valid methodology.

It's black letter law in the administrative law context, as the Court is well aware, that an agency has to have some type of concrete methodology so that the Court can assess whether that complies with the statute, whether the

agency has carried it out, and whether the evidence actually supports the agency's ultimate decision. Without that, an agency's action is inherently arbitrary. And so that alone requires vacatur.

But the FDA's specific choices here raise even more questions that the decision doesn't even attempt to answer.

THE COURT: Is it fair to say, you contend that the FDA, essentially, picked and chose what type of data it wanted to relate to to get to the ultimate answer? Is that a fair way to -- they got to the answer that they wanted by cherry-picking the data; is that a good way to describe your argument?

MR. GROSSMAN: No, Your Honor. I don't think that's quite right.

THE COURT: Okay.

MR. GROSSMAN: Our argument is that Eli Lilly picked and chose the data that it wanted to present to the agency, and then the agency said, Yeah, that looks good enough to us. In other words, the agency didn't say, Here's the standard that we're applying and does the evidence support that standard? In other words, the agency --

THE COURT: And you're correct, that's what I meant to say. You said it much more artfully than I did.

Go ahead.

MR. GROSSMAN: So, let's begin just with the simple

issue of a period of time. The Court, in its preliminary injunction decision, and now FDA and Lilly, say that the agency analyzed supply and demand over the [redacted], even though that only covers one of the sets of data on which the decision relies.

First of all, the agency made no finding of demand over that period of time, that [redacted], or really over any period of time. The agency made no finding of supply over the [redacted]. Instead, the decision finds [redacted], even though the defendants can't point to any record evidence that supports that figure. But put all of that aside for the moment.

Why use a [redacted] of analysis to begin with to assess whether a drug is currently in shortage? There is not a single word of explanation in the entirety of the decision to justify that choice. It certainly isn't obvious. The [redacted] is not in the statute or a regulation. FDA and Lilly can't point to any other process, any business practice, or anything of the sort that typically employs a [redacted].

There's no explanation by the agency as to how diluting current data with stale data from [redacted], is somehow consistent with undertaking an up-to-date determination of shortage status. There's also no

consideration of obvious alternatives: Month to month, bimonthly, quarterly, six months. We're not just making up these potential alternatives, other sets of data that are in the decision are framed in those formats. So, those were things that were already before the agency, and the agency just didn't consider. If it did, in fact, choose the [redacted] of consideration, it didn't address those alternatives.

And I want to be clear, that this is not a minor detail of the decision. The choice of time period dictated the outcome. If you run the same methodology that the decision employed, in other words, looking at this aggregate supply-and-demand data, and that's at least a part of the decision, if you apply that methodology over a more up-to-date time period, like month to month, two months, a quarter, or even the most recent six months, the results come out negative.

And so --

THE COURT: I know that one of the big things you focus on is you fault the FDA for not considering Eli Lilly's delays in shipping as an indicator that the shortage was continuing -- I'm sorry I'm not speaking into the microphone -- and you also criticize the time period.

Is there -- tell me a better alternative. What would be a more reasonable alternative to the time period they used? And the reason why I ask that, contrary to what you may

read about me or any other judge in the newspaper, I really -- when it comes to the Federal judge who was a political science major from a state university going and telling the FDA maybe they didn't do their methodology correctly, to quote our late Pope, Who am I to judge?

What -- what's your alternative? It's easy to criticize. It's easy to be in my position, and say, Well, the time period they used was arbitrary and capricious. But what would have been a proper, reasonable time period to consider in this case? Do you have an alternative?

MR. GROSSMAN: So, if I could, Your Honor, I would give you two answers to that question. The first is simply that the agency has to justify its choice. And I agree with you that it's not the role of the Court certainly to supplant the agency's exercise of discretion.

The Court's role is simply to determine whether the agency properly exercised its discretion. And for the Court to undertake that inquiry, it has to rely on the explanation provided by the agency; and in this instance, there is none. So, that's kind of the problem here.

Maybe the agency could justify a [redacted], maybe it couldn't, who knows. But the problem is, is that the agency didn't even try to do that. That said, we think that the [redacted] is, at a minimum, intentioned with, if not in violation of, the statute.

As the Court's well aware, the statute requires an up-to-date determination. If you give equal weight to data that is [redacted], as you are giving to the absolute most current supply-and-demand data, that necessarily dilutes the effects of the more recent data. And so, the farther back that period goes, the less up to date the decision is actually going to be. So, there may well be a statutory violation here. But, again, the agency never explained how it was to reconcile its apparent choice, as the Court indicated, of a [redacted] with the statutory requirements of an up-to-date determination.

So, it's not our place to say, Here's exactly what the agency should have done. We think there are some obvious alternatives it had to consider; as I said, month to month, bimonthly, quarterly, maybe six months. Those are sort of obvious. Other data is in those formats. A reasonable agency would look at those and say, Maybe that's better, maybe that's worse, let's work through it and come to a reasonable answer.

THE COURT: And at the same time, it's not the Court's job, if I grant your summary judgment, to say, A better alternative would have been X, quarterly or whatever.

MR. GROSSMAN: That's correct, Your Honor.

Well, except I would say, that there is at least -- so, again, I apologize, in blurrily fashion, for giving two answers, but they're different --

THE COURT: No, that's fine.

MR. GROSSMAN: But they're different theories.

THE COURT: Yeah.

MR. GROSSMAN: So, it would be enough for the Court to say that the agency's choice of a time period is simply unreasoned. And it would be enough for the Court -- that would be enough for the Court to vacate and say, You have to provide some type of explanation, if you can explain this choice.

If the Court wanted to reach the statutory issue, again, we think there's a real problem with choosing a [redacted] that looks back so far. And so the Court could also say, That, at least as the agency has failed to explain it on this record, that it is -- that it is in violation of the statute for the agency to choose that time period.

But I want to stress, in that instance the Court would not be in a position to supplant the agency's discretion and say, Here's the time period you have to use. It would be just be enough to say, The one that you selected does not comport with the statute.

So, as I said, this is not a minor detail. This choice of time period actually drives the outcome, at least with respect to the supply-and-demand data. But, again, I think there's a problem with that data. The agency relied on

[redacted] But Lilly conceded on the record, as well as in its briefing, those figures [redacted]

So, when Lilly, in its briefing, talks about a [redacted] and things like that, its submissions to the agency, as well as its briefing, admit that, no, [redacted] They don't correspond with any real-world fact.

So the question here, in other words, is, Why use a statistic to represent supply that doesn't match the ordinary meaning of that word or the purpose of the statutory inquiry? Maybe the agency has some kind of answer for that, but it's not on the record, it is not in the decision. The agency had to explain that.

[redacted] Again, there's no explanation to justify that choice.

[redacted] Again, there's no explanation.

And why accept Lilly's unsupported assertion of being able to supply [redacted], which is [redacted], according to its own data, in any month? Again, there's no explanation whatsoever.

Now, FDA, in its briefing, emphasizes its discretion in addressing shortages. In other words, it gets to make policy with respect to shortages.

THE COURT: Let me ask you on the [redacted] Because I think the FDA counsel is going to come and say, Mr. Grossman is wrong, that was not totally the FDA relying on Eli Lilly data, rather that was the FDI -- I'm so sorry -- the FDA taking the projected data given them by Eli Lilly and they came up with the [redacted].

MR. GROSSMAN: That's not correct, Your Honor.

The actual [redacted] was in response to a question provided by the FDA. And the letter response from Lilly, from which that number is drawn, stated that Lilly is [redacted], and that that would -- that number was going to be explained later in the letter; which, in fact, it never is explained. And so, there's actually nothing in the record that supports that.

The evidence that is in the record is Lilly's actual -- at least Lilly's reported [redacted] supply, none of which actually come close to [redacted] --

THE COURT: I think that's a very important argument. I hope my defense counsel, particularly FDA counsel, addresses that.

Go ahead, sir.

MR. GROSSMAN: And I will note, in addition, in its briefing, the only thing that the FDA is able to say about that, is that it considered Lilly's representation of that to be "credible."

THE COURT: And why isn't -- why do you feel it's unreasonable for them to be able to rely on the representations of Eli Lilly with regards to the -- for example, the [redacted]?

MR. GROSSMAN: Well, first of all -- I mean, for something that is such a key factor in the inquiry, that's something where evidence is actually needed, rather than simply the assertion of a self-interested party.

Second, that number conflicts, because it is [redacted].

And then -- and then third, Lilly's projections, Lilly has one projection for [redacted] that is substantial -- that is [redacted], I believe it's [redacted], or thereabouts. But then every other supply projection, [redacted]

[redacted]

So, I think it would be enough to say that it's not credible. Because if the agency simply looked at Lilly's other submissions, it would, at a minimum, raise questions about how this comports with what the -- with what Lilly has actually done to date, as well as what Lilly projects going into the future.

But I think the bottom-line point here is that in all of these choices, or lack of choices, the agency was exercising its discretion. And we don't disagree with the agency that it has discretion here, it gets to make policy with respect to shortages, it gets to make a shortage policy. But when an agency is making policy in this fashion and it's exercising its discretion, it has to explain how and why it exercised its discretion; and the FDA failed to do that at every turn.

So, I'd like to move on to addressing some of the record evidence here. First, Lilly's data, and then second, some of the data that was supplied by other parties. As I've described, Lilly's supply-and-demand data, this cumulative data that was supplied to the agency is not up to date, but it's stale. Any reasonably up-to-date listing, or any reasonably up-to-date tally that uses the last six months, or any period shorter than that, would show demand outpacing supply. In other words, what the FDA has defined as a

shortage.

There is, as I described, no record evidence supporting FDA's finding of a [redacted]. Lilly admits in its briefing it never has manufactured that much. And the FDA's point is, Well, it deems that to be credible. The FDA -- I'm sorry, the APA requires substantial evidence. Here, there is literally nothing.

But I want to emphasize to the Court why that figure actually matters. Lilly's demand projections -- if you look at its [redacted]. And that's without even considering the demand that was being currently satisfied at that point by compounded products.

FDA's rationale for its conclusion that compounded supply ultimately didn't matter in the analysis, was that Lilly could [redacted], which it said was enough to meet any potential supply that would transition from compounded products to Lilly's products. But, as I said, there's simply no support for that -- for that underlying -- for that [redacted] figure in -- in the record evidence.

Then there are Lilly's inventory snapshots. The problem here is that they measure supply, not demand. I want to make clear, they do net out orders that were open at the

precise moments that the snapshots were taken, but they aren't paired up with any commensurate measure of demand.

And Lilly admits in its briefing, as well as on the record, [redacted] at a time. And that's likely why, if you go through the record, [redacted]

Lilly's shipment data shows a [redacted] -- again, Lilly reported demand -- in [redacted] a [redacted]. The FDA's briefing -- and this is FDA's opposition brief -- says, Well, who knows, it's possible that those data sets might cover different time periods. Lilly's opposition brief, and this is page 17 of that brief, [redacted]

THE COURT: Let me ask --

(Court Reporter interrupts)

MR. GROSSMAN: I apologize, page 17.

THE COURT: And I interrupted, I apologize, too.

Let me -- let me take you back to this contention about the -- [redacted] and the [redacted] that you're contending there that is evidence that I should rely on to show that they acted arbitrary and

capricious. But in looking and comparing, I think it was chart four and five in your brief, one of those charts dealt with [redacted]; and on the second chart, it dealt only with [redacted].

So, is that something that's really as important as you are arguing? In other words, would that account for the difference in the [redacted], because you're not comparing the same shipments in both of the charts?

MR. GROSSMAN: Your Honor, the answer is we don't know, because the agency never asked them and that data isn't in the record. The -- according to Lilly, the difference between the two data sets is that the -- is that one of them includes -- I'm sorry, [redacted]

THE COURT: Yeah.

MR. GROSSMAN: [redacted]. Is it plausible that there is a [redacted]? I don't know. I think, at the very least, one could say that that raises serious questions that the agency should have asked. And it's the kind of thing that you would expect to see addressed on the record, particularly --

THE COURT: In other words, more -- more evidence that they didn't act reasonably when it came to making a

decision?

MR. GROSSMAN: That's exactly --

THE COURT: Reasonable agency action would have asked those questions.

MR. GROSSMAN: There was all kinds of indicia on the record that there were problems, that there were shortages in different areas, that people were having problems obtaining access to these products. And that's sort of -- that would prompt any reasonable agency to do as much as it could to compare the different sorts of data that it receives and see how they line up. In other words, see if there's consistency.

If Lilly is reporting shipments, well, of course you look and see how that matches up against demand. And if there's some discrepancy there, as there was in this instance, a very large one, the natural thing would be to ask -- to ask Lilly why. That's something the agency never did in this instance.

And then, finally, the decision relies on Lilly's completely unsupported claim that wholesalers, by [redacted]. That is directly contradicted by the screenshot data, which shows that wholesalers limit orders when they lack stock. In other words, a pharmacy cannot place an order from any of the major wholesalers, when the wholesaler lacks the capacity to fulfill that order.

And so, the fact -- so the agency was relying on a fact from Eli Lilly that has, effectively, no significance whatsoever, as demonstrated by evidence that was on the record by the agency.

And I think that's a good segue to talk about some of the evidence from the wholesalers. To begin with, this so-called screenshot data shows widespread unavailability in November and December. Many of these screenshots are identified by the FDA and by Lilly as being from [redacted]. [redacted]

[redacted]

FDA and Lilly claim that these low-stock and out-of-stock situations were short lived --

THE COURT: Well, counsel, if the test here is just really reasonableness, why -- why would it not be reasonable for them to -- at least I'm anticipating what they're going to argue, the FDA, that rather than relying on the screenshots we relied on the comprehensive data.

How do you respond to that argument?

MR. GROSSMAN: Because there's an inconsistency. If you have major -- if you have major wholesalers that are supplying, in this instance about a third of the market, and that according to the record, materials distribute through effectively a hub-and-spoke system, a centralized system, and

they have pervasive, ongoing shortages, that shows that there is something seriously wrong with the supply of the drug. And again, at a minimum, you would expect that to prompt the agency to make further inquires.

We think looking at it that if one of the Big Three Wholesalers has extended periods of a drug unavailability, that, in and of itself, under the statute, in all likelihood, would support a finding of shortage itself.

But I think the real -- but I think a more direct answer to Your Honor's question, is the way the Court should look at this is to evaluate the FDA's analysis of this question. Part of the FDA's analysis was simply saying, We think Lilly's data is better, and that it doesn't detract -- that this evidence doesn't detract from the weight of that. But, of course, we've already discussed some of the deficiencies and shortcomings of Lilly's data.

But it has more specific responses that, I think if you look at them closely, don't actually hold water. For the [redacted]. But that actually says nothing about whether a given dose, a given product, is in shortage or not. In other words, if that supply across all wholesalers is less than the demand on the market, well, then, of course, there is a shortage.

(Court Reporter interrupts)

THE COURT: And, really, I'm going to be generous with the time. I know that you feel like you're rushed. I'm going to give you all the time to make your argument that you need, okay?

MR. GROSSMAN: Thank you, Your Honor.

THE COURT: And it may just be, we're southerners, so we speak slower. I'm married to a New Yorker, so I get it.

MR. GROSSMAN: I will try, Your Honor, to arrive at a happy medium.

THE COURT: No, it's okay. It's all right.

And my New York wife, she's also Sicilian. So, I'm used to being told that, I can't understand you, you speak too slow. So -- but don't take any offense to it.

In fact, I got in trouble last night because we wanted to order some Greek food. And I told the -- when I called it in, I said I wanted ten pita bread, and I only got two. And my wife chewed me out and she said, Nobody ever understands you, you've got such a hick accent.

So, don't take offense. I get it. We talk slow, we think slow, but we'll get everything down, I promise you.

MR. GROSSMAN: No offense, Your Honor. And Your Honor's rulings have been fast -- in fact, been very, very expedient.

The FDA, with respect to these November screenshots, part of its response also cites Lilly's assertion that it

[redacted]. But even accepting that to some extent, there's nothing to show that Lilly did provide or even was able to provide enough supply to meet the demand so that pharmacies actually obtain the products in question. And, in fact, the evidence shows that they can't.

First, there are, as I mentioned, a wrath of screenshots from December, including from the same exact wholesalers. So, in other words, these December screenshots show unavailability a month after Lilly said that it resolved the issues.

Second, and I think this is even more telling, many of the December screenshots from [redacted] identified, not only when a notice of unavail- -- excuse me, unavailability was updated, but also how long the "product issue" was being tracked by [redacted] So, for example, there's a screenshot at page 668 of the plaintiffs' appendix, and it shows that the specific dosage at issue had a product issue, which specifically was being out of stock, that began on October 23rd, and that it was most recently updated on December 10th.

Similar screenshots, showing extended product periods of unavailability running through December 10th, shortly before the decision in this case, are in the plaintiffs' appendix at pages 680, 667, 669, 679, 682, and

714.

THE COURT: Tell me that -- I want you to tell me those one more time, counsel.

MR. GROSSMAN: Yes, Your Honor.

THE COURT: Go ahead.

MR. GROSSMAN: So, 668.

THE COURT: Yes, sir.

MR. GROSSMAN: And then 680.

THE COURT: Uh-huh.

MR. GROSSMAN: 667, 669, 679, 682, and 714.

THE COURT: All right. Thank you.

MR. GROSSMAN: And that's in addition to the notations in many of the screenshots from [redacted] indicating that the products in question wouldn't be available either from an undetermined period of time or for months.

Now, none of those specific -- specific dates and representations that are on the face of this screenshot evidence, none of those are actually addressed in the decision itself. The FDA simply waived away this entire category of evidence without even attempting to address or explain what it shows on the face of it.

Finally, I'd like to briefly address, or at least make a few points, with respect to our notice and comment claim. The agency's position here is that this was not a legislative rule, but it was instead an adjudication. We

think that as a legal matter it couldn't be an adjudication for at least two reasons. The first is that the action -- the agency action here makes prospective law by prohibiting certain types of compounding going forward by all compounders, including pharmacies that aren't even compounding today.

I mean, the way an adjudication works, is that it adjudicates the rights of a person who is before the agency --

THE COURT: Tell me what you think your best case is on that argument.

MR. GROSSMAN: Our best case on that argument, we cited all over the place, Your Honor, but it is the *Safari Club*. We think that *Safari Club* is effectively indistinguishable, in that it concerned a factual determination by the agency that was made outside of the context of an adjudication involving the rights of a particular party. And then that factual determination triggered legal consequences that applied in subsequent proceedings. That's exactly what happened here.

The agency made a factual determination, based on its policy views, that, in turn, triggers legal consequences, so that makes it a rule, in general, and those apply only prospectively. In other words, what people were doing up until that day is not affected whatsoever by the agency's determination. It could -- that new rule could only be applied prospectively to future conduct.

For example, if an outsourcing facility were to continue compounding from Tirzepatide, then it would be presumably an enforcement proceeding where this new rule would then be applied against it.

THE COURT: Okay.

MR. GROSSMAN: But here, nothing was applied against any party whatsoever, because -- and this is a novel thing about this -- the agency's argument in this case, there were no parties before the agency in this proceeding.

We've argued this consistently, and the FDA has never disputed in its briefing that there were no parties to the proceeding that it conducted. It just says that that doesn't matter, even though it can't identify a single adjudication in the history of the Administrative Procedure Act that involved an adjudication with no parties before the agency at all.

THE COURT: Let me stop you, counsel.

One of the things that I would like FDA counsel, and maybe my in-house FDA counsel, could enlighten me on, when we have been doing our research when it comes to this case, is the frequency in the history of FDA, this type of proceeding involving shortages, we haven't been able to find any. I'm not saying that it doesn't happen, it may be the first time that this has been challenged in this type of context. But I'd like to know, I think it would just help me. I'm not

making any judgment one way or another, I'm just curious.

Go ahead, counsel.

MR. GROSSMAN: Thank you.

Lilly, in its opposition brief, for the first time claims that it was actually a party to this proceeding. The FDA, evidently, at least going by its briefing, disagrees with that. And for what it's worth, the delisting action here doesn't adjudicate Lilly's rights whatsoever. Lilly can still do everything that it did before the action was issued.

Second, the Court relied, in its preliminary injunction decision, on the statutory language that the shortage list be kept up to date. We think that that particular requirement doesn't really have anything to do with whether a proceeding is a rulemaking or an adjudication, which concerns the forum of the proceedings. At most, the right way to frame this, the right way to think about it, would be whether -- whether that requirement somehow abrogates and overcomes the APA's ordinary default notice and comment provisions. But that's not a ground of the decision here. That is not what the agency argued in its order.

Also, the language here, up to date, doesn't satisfy the standard for expressly departing from the APA's standard -- standard procedures for rulemaking or for anything else. The statute, on its face, identifies bases for shortage -- for shortages, liked planned discontinuations of

manufacturing, that allow more than enough time for notice and comment.

There are -- there is the related shortage notification provision of Section 506C, that contemplates proceedings that unfurl over a period of weeks or months, not just days.

For example, it provides, on its face, 30 days for a manufacturer to respond to an FDA determination, that the manufacturer has failed to report a shortage and failed to provide the needed information to the agency. So, this isn't unfurling at a breakneck speed, it's going a more leisurely pace that is commensurate with the time available for rulemaking under standard procedures.

But I would note that courts -- that when Congress has commanded that something be done expeditiously, courts have not insisted on the standard rulemaking timelines. When Congress has used words like expedited or without delay, the courts have allowed comment periods of as little as 15 or 7 days.

We cited, as an example, the *Omnipoint* decision by the D.C. Circuit, but that cites a number of other decisions along similar lines. And if even that was not feasible, a seven-day comment period, then in that particular instance the agency would clearly have good cause under the APA itself to forgo notice and comment. So, there's nothing in here that on

its face conflicts with, let alone dis- -- expressly displaces the ordinarily applicable notice and comment provisions.

The Court also addressed the use of confidential materials in -- in certain types of shortage decisions. The confidentiality provision in the shortage statute simply says that it does not abrogate generally applicable laws that apply to all rulemakings. In fact, one of those -- one of those two statutes that it cites, the generally applicable ones, one of those is part of the APA itself. There's simply no indication that by citing generally applicable statutes that apply, again, to every single rulemaking that occurs, that that manifests any sort of intent to override the APA and its standard default procedural provisions.

Moreover, the statute contemplates delays that likely would not even involve any confidential information. For example, shipping delays, regulatory delays, discontinuance of manufacturing. And I will note, as well, that the use of confidential material in rulemakings is incredibly common.

I, myself, just the other day, went to federalregister.gov, and I just did a search for confidential business information and final rules and proposed rules, there were over 1,000 hits from 2024 alone. Most of those -- or at least many of them, hundreds of them, cite one or both of the two generally applicable statutory confidentiality provisions

that are note -- that are referenced in the statute that's at issue here.

I will also note in my own experience, as well as in case law, the use of confidential information does not prevent meaningful public participation through notice and comment. Agencies do this all the time. What agencies will do when they're relying on confidential information, they will summarize, they might put it in aggregate form, they can describe it qualitatively. For example, Lilly's data show that on a cumulative basis, supply is outrunning demand.

THE COURT: Believe me, I get it. I couldn't even access the Fifth Circuit decision in this case until -- what was it, John?

LAW CLERK: Ten days.

THE COURT: Ten days after it was made. So, I get it. I get your point.

MR. GROSSMAN: The point is, agencies do this every day of the week.

THE COURT: Yeah.

MR. GROSSMAN: And not only can they discuss data in that way, when disclosing the data itself would be confidential, what they could also do is they could disclose their methodology, their proposed conclusions, and they can identify what information the agency considers relevant to the question before it and how it's going to consider that

information.

THE COURT: I'm very familiar. I bet Ms. Lewis *(sic)* is familiar with another case -- or another two cases that I have involving FOIA requests and the FDA. So, I get what you're saying. I get the point.

Let me get you to wrap up, if you can, and then I'll maybe ask you a couple of questions that come from my old Court of Appeals days.

So, go ahead, sir.

MR. GROSSMAN: Yes, Your Honor.

I just have one final point to make, and that's regarding what the Court called the lose/lose scenario. In that, the original shortage action was not undertaken through notice and comment.

Perez makes clear that the process -- that the procedure that's required to amend or repeal a rule is the same that was required to enact it, to promulgate it in the first place. So, this isn't an instance where two wrongs make a right. And that can't possibly be the result, because it would mean that all kinds of tax regulations would be invalid instantly.

But even going beyond that, the Supreme Court's decision -- let me say two other things on this. One, the agency, in its delisting action, didn't identify the validity of the original shortage -- the original shortage action as a

basis for its decision, and that original action is not before the Court in this case. So, nobody has challenged it, we think that probably nobody would have standing to challenge it, but that would have to be some other case.

And even if the agency had mentioned that as a ground, it couldn't simply say, We're going to disregard it or abandon it, or something like that. The Fifth Circuit explained as much in the recent decision *Louisiana vs. Department of Energy*. That even when a rule may be invalid, the agency can't simply say, We're getting rid of it for that reason, it has to consider alternatives. For example, fixing whatever the legal problem might be.

So, we don't think the issue is properly before the Court of the validity of the original action in this instance. But even if it were, I don't think it would change the result in this case.

THE COURT: All right. Not to pin you down, but I'm just curious, what you think -- what do you think, out of your many arguments in favor of summary judgment, what do you think is the most compelling of the counts you've presented to the case? What would you say is your best argument or your -- point me in the record your best piece of evidence to show that the FDA fouled things up?

MR. GROSSMAN: Your Honor, the way I would answer that question is to identify what I think is the easiest

ground for the Court.

THE COURT: That's what I like, easy stuff.

MR. GROSSMAN: And I think that is really going to be our second claim, which is simply lack of reasoned explanation. There's a reason we led with that in our summary judgment briefing, and that's because it's apparent on the face of the decision. The FDA inherently made all kinds of determinations and undertook a methodology that is never described and doesn't appear to have substance to it whatsoever.

THE COURT: So, could I grant your motion for summary judgment on Count 2 and leave the notice and comment versus adjudication, going down that route, could I leave that alone and still get to where you want to go?

MR. GROSSMAN: Yes, Your Honor.

The Court could do that, and that would be a basis to vacate the rule, and in that -- I should say, vacate the action. And in that instance, that would resolve the case.

THE COURT: Okay. I appreciate it. I may have some more questions for you. But thank you for your thorough argument, sir, I appreciate it.

MR. GROSSMAN: Thank you, Your Honor.

THE COURT: All right.

I guess now I'll hear from FDA counsel, Mr. McDonald.

MR. MCDONALD: Good afternoon. Thank you, Your Honor, for the --

THE COURT: And I'll do my best not to interrupt, but I do have some questions.

MR. MCDONALD: Sure. Well --

THE COURT: And hopefully some of my questions to Mr. Grossman may have prompted -- you can tell what I'm curious about.

MR. MCDONALD: With the Court's permission, I'd like to start with the statute --

THE COURT: Yeah.

MR. MCDONALD: -- because I think that answers some of the questions before the Court.

THE COURT: Yes, sir.

MR. MCDONALD: The statute directs the FDA to determine whether there is a shortage. And it says, A shortage is when the demand or projected demand for the drug within the United States exceeds the supply of the drug. The statute itself gives the FDA the parameters it needs to make the decision it is tasked with making.

And here are the facts on those parameters at the time of the agency's decision. The most recent information available to the agency was that after fulfilling all open orders, the manufacturer had [redacted] on hand. And at that same time, the manufacturer also

had [redacted], which the manufacturer said could quickly be made into finished product to adjust to the variations in demand.

Those snapshots of net inventory had a increasing trend over the period of time that the agency evaluated it, it had several months of those snapshots, but that wasn't all the agency looked at either. It also looked at the cumulative data that showed that over a longer period of time, Lilly had improved its ability to adjust to the demand and continued to meet the demand. Some of those cumulative figures also projected into the future, and indicated that Lilly could also meet the increased -- anticipated increased demand in the future.

FDA had good reason to rely on those projections, because it received that information over a period of time and was able to see that the projected numbers for one month ultimately [redacted]

THE COURT: Can you describe to me as a general matter -- I'm assuming -- back in the old days when I was a DOJ attorney, I was responsible for doing -- oh, my main area was doing anti-dumping cases, tariffs, products from China, specifically garlic and pencils from China, of all things. So, I presume you -- it's fair to say that you have an area of expertise at DOJ and I presume it's these FDA actions; is that

fair to say, sir?

MR. MCDONALD: It's reasonably fair to say.

But to answer one of the Court's questions, to anyone's knowledge, this is the first time a drug shortage decision has ever been litigated.

THE COURT: Well, you're smart, because that was the question I was going to ask. How many of these have you had, how often do we have these?

I have not been able to locate one, so you've answered my question. I shouldn't have told you the long-winded story about Chinese garlic.

Go ahead, sir.

MR. MCDONALD: Well, to answer the Court, it's only the two pending before Your Honor, are all the ones I'm aware of.

THE COURT: And that's the same thing from my FDA counsel?

MS. LOVAS: Yes, Your Honor.

THE COURT: So, it's fair to say this is not something that's, at least in your experience, is commonly done at the agency?

MS. LOVAS: Litigating this issue?

THE COURT: Just in general, not even litigated. I'll take your word for it, this is the only two that have ever been litigated.

Just in general, is this -- I don't -- this is the first -- well, that and the companion case that I have, the APA challenge I've had involving FDA. So, just educate me. Taking litigation out of it, garden-variety case like this. Do these go on often, where the FDA is determining whether the shortage is over? I guess that's a good way to say it, maybe not.

MR. MCDONALD: Your Honor, the more --

THE COURT: Outside of litigation or that they've been challenged.

MR. MCDONALD: Your Honor, the more common scenario is when there's some sort of event that disrupts the ability to manufacture. Like a tornado takes down the only manufacturing facility and that drug is, as a result, in shortage for a period of time. That's the more typical instance of a drug shortage and --

THE COURT: And I guess in a case like that, it would be much easier to determine whether to end the shortage because the Skyrizi factory is back online or whatever, right?

MR. MCDONALD: Or at least it would be different criteria. I'm not sure how difficult it would be, since that hasn't come across my desk.

THE COURT: Okay. So, it's fair to say that this is -- I can't think of another word -- but fairly unprecedented for everyone involved. I don't -- certainly in my lifetime, I

can't think of products similar to the Tirzepatide and also the semaglutide products that have had the popularity that they have had and the demand that's out there.

And I would -- that's helpful to me. I was just curious if y'all had been down this road before. I would assume this is fairly unprecedented due to the popularity of these drugs; is that fair to say?

MR. MCDONALD: I look to agency counsel to correct me, but it is typical to assess the volume of the demand and when the supply comes back online, whatever the reason was for the shortage in the first place. What would be unusual here is just the runaway demand for the drug --

THE COURT: And that's what I was trying to say.

MR. MCDONALD: That's accurate, Your Honor.

THE COURT: Okay. I didn't want to get you off your argument, I just -- it's helpful for me.

Go ahead, sir.

MR. MCDONALD: Not at all.

So, I wanted to actually circle back to that snapshot, the most recent snapshot evidence, and respond to something opposing counsel mentioned. It does reflect, in some sense, the demand for the drug. Because Lilly represented that it was not limiting the wholesalers' orders at all. So, when that -- when those numbers reflect that it is net inventory, that all open orders have been fulfilled,

that means every wholesale order we have as of that time has gone out. So, it's not accurate to say it doesn't reflect demand, at all.

So, I described some of the snapshot evidence and some of the cumulative evidence. That -- that was ample evidence for the agency to conclude -- looking back at the statute, whether at that moment was supply now outstripping demand and was supply projected to outstrip demand.

THE COURT: Okay. So it --

MR. MCDONALD: That's the --

THE COURT: It's helpful for me, because remember we're here on summary judgment. I asked similar questions to plaintiffs' counsel. But can you point me to the most salient evidence that you would have that FDA could rely on to show that this surplus would continue past the projected window that they looked in?

Like, is there evidence on the record, do you know of a -- what's the best thing that the Court can look at, and I can say, Yeah, you bet, the FDA was reasonable here, looks like it's reasonable to believe that this surplus would carry on past the time period they looked at. What do you think is the best piece of evidence that I can look at?

MR. MCDONALD: To confirm I understand Your Honor's question, the projected charts in the decision memo that the FDA relied on, they were projected through [redacted].

Is Your Honor asking about a period [redacted]

THE COURT: Yeah, because I think that's important. That if you're saying the shortage is over, Eli Lilly has the exclusive right to do this, we're not going to allow people to compound it anymore, seems like to me you'd have to have a basis that the shortage was over for a reasonable time period.

MR. MCDONALD: Well, as of the decision, that projection was [redacted]. So, [redacted] that Lilly would continue to meet the demand.

And something that --

THE COURT: What about in [redacted] it looks like they're not meeting the demand?

MR. MCDONALD: Well, that's something that FDA --

THE COURT: Everybody is trying to get in shape for their bathing suits to go to the beach this summer.

MR. MCDONALD: Of course. Well, that's something FDA addressed in both the declaratory order and the underlying decision memo. It said in both places, the agency is going to continue to monitor the supply and demand.

And there is possibility that it's [redacted], the prediction didn't prove correct, FDA could have declared a new shortage. But in that intervening time when Lilly was -- the FDA reasonably found that Lilly was meeting demand, at least for those [redacted], going to meet - continue to

meet demand, that's no reason to maintain that a shortage exists simply because we can't look six months in advance. It's better and more faithful to the statute for FDA to continue to monitor and declare a new shortage if that comes out.

THE COURT: Okay.

MR. MCDONALD: So, that's -- I'm happy to answer more questions about Eli Lilly's data, but otherwise I'd like to turn to some other information.

THE COURT: No, I want you to make your argument.

MR. MCDONALD: Sure. So, the agency had a number of other pieces of information before it. Much of it was third party or anecdotal, unverifiable, otherwise not probative, and does not show the sort of pervasive shortage that plaintiffs are alleging it does.

Turning to the screenshot evidence, as set out in our briefs, some of those screenshots are duplicates of each other. Some of them aren't dated, some of them are. Some of them are about a different drug entirely. And some aren't about the wholesalers at all.

So, I'll focus on the ones that plaintiffs brought up, in the most recent briefing and just now. I'm looking at plaintiffs' appendix 682, one of the cites that counsel just invoked. That's also administrative record 1544. It's -- it shows the stock for Mounjaro and Zepbound. For the

5-milligram dose of Mounjaro, says it's in stock. For the 7.5-milligram dose of Mounjaro, says in stock. And I can go all the way down the list, it's in stock as of that moment.

Now, sure, there's a -- there's a notation on the website that warns a visitor that -- my read is that supply is tight. But to say that this screenshot that shows the product in stock, or seven other screenshots shows a pervasive shortage, is stretching the evidence pretty far, Your Honor. And FDA reasonably relied on the much more detailed and reliable information from the manufacturer.

Some of the other third-party evidence suffers from similar defects. Like the surveys where there was not information before the FDA about who was allowed to complete the survey, were multiple people allowed to complete the survey, what do the questions on the survey even mean.

The most important third-party information before the agency was about the volume of compounding. And just to address that briefly, FDA accurately used that to evaluate whether Lilly would be able to continue meeting the projected demand.

THE COURT: Is it reasonable for the agency to rely so much on the representations of Eli Lilly?

Couldn't you make an argument that given the demand for this product, given the large percent of the population that needs it for health reasons, it would be arbitrary just

to rely upon the numbers that you were given by Eli Lilly, rather than other third parties, or for that matter, greater level of interaction with Eli Lilly where you have boots on the ground verifying versus, all right, this is what their charts show us? Why is that not the more reasonable thing to do?

MR. MCDONALD: I disagree. I don't think it could be per se unreasonable or arbitrary and capricious to rely on information from one party.

But here, the record shows that FDA interrogated the responses it got from Eli Lilly. And in some instances, it refused to consider some of the information that Eli Lilly put before it.

For example, Eli Lilly [redacted] And FDA said, Well, we don't have comprehensive information about that to rely on it, we're not going to rely on it.

Eli Lilly said, Look, [redacted]. And FDA said, [redacted], and we're not going to consider that for the purposes of our decision.

In another instance, Eli Lilly provided information that was simply drug by drug and not broken down by dosage.

And the FDA came back to them and said, We actually need to see this disaggregated, broken down.

And further, the credibility of the information from Eli Lilly was, as I mentioned before, proved out over time. It wasn't only one tranche of evidence taken from Eli Lilly. There was instances where Eli Lilly said, We think this is going to happen, and then time went by and FDA was able to go back and verify that it was reliable.

So, under all of those circumstances, it was completely reasonable for the agency to rely to the extent it did. And I'd add that it had very little choice, other than to get the information from the manufacturer and interrogate it as it did.

For a couple of reasons, due to the nature of this shortage it was the most important information. The person with the information was Eli Lilly. And the second reason is that FDA was under a statutory obligation to act quickly. The list must be kept up to date.

So, it's easy for us to sit here with the luxury of time now that the baseball game is cancelled and think of ways that Eli Lilly could have looked at this -- or sorry, FDA could have looked at this, could have asked Eli Lilly this question, but the agency was under that time pressure.

So, once it had information that reasonably showed that the shortage was over, it was under a statutory

obligation to -- to issue that decision.

THE COURT: I would rather be at the baseball game, by the way.

(Laughter)

MR. MCDONALD: I don't blame you, Your Honor.

THE COURT: Or maybe not. They got -- as bad as they're playing, I doubt if they'd win if they did play.

(Laughter)

MR. MCDONALD: Well, we've set out --

THE COURT: They got a run ruled the last game and somehow they have like a four and ten record, but they made the playoffs. I don't know who is doing the math on that, but I don't know.

MR. MCDONALD: Well, we had some more detailed arguments in our briefs about, for example, the rulemaking versus adjudication point. I'm happy to address, if the Court has a question.

THE COURT: Yes.

If you couldn't tell by the answer -- or rather by the question that I asked Mr. Grossman, I understand the arguments made arguing that this is -- whether its adjudication versus notice and comment. I spent some time reviewing the *Safari* case. But I am a little bit hesitant to go deep into that argument.

I do feel, to a certain extent, it would be plowing

some new ground, which -- I'm certainly not afraid to get reversed, I get reversed all the time. But I am loathed to try to go out and essentially -- a Judge shouldn't say this, but I can't think of any other way to say it, make new law, interpret laws in ways it hasn't been interpreted before.

And I've never seen -- and I know, taking the *Safari Club* out of it, I do think that this case is distinguishable. But at the same time, I understand the plaintiffs' arguments, and it does bother me.

So, make your argument there. I'd like to hear from the Government.

MR. MCDONALD: Well, I don't think your Honor has to worry, in part, because that case is distinguishable. One important feature of the dispute in that case, is that the challenged decision had purely perspective effects. It said, In the future if somebody wants to do this thing, they're not allowed to do it.

Whereas, in this case and similar cases, there's ongoing conduct here. And this is something plaintiffs have mentioned ad nauseam, ongoing conduct that must cease because of the resolution of this dispute. And that's not purely perspective at all.

And the second reason, is that the Fifth Circuit has addressed declaratory orders a number of times, as in the *American Airlines* case cited in our brief. There's also a FCC

case that has to do with citing certain communications equipment and local -- local approvals of that, and setting time limits for how quickly a local government has to act on certain applications.

And those, similarly, just going -- going to the declaratory adjudication statute, that's 5 U.S.C. 554(e), that's the agency "in its sound discretion" issuing a declaratory order to terminate a controversy or remove uncertainty.

And the declaratory order in the adjudication context serves a really useful purpose. Because it prevents the agency from needing to go out and doing an adjudication as an enforcement action just to answer, for example, a jurisdictional question about the agency; or in this case, no compounder needed to risk enforcement, just for anyone to find out whether the shortage was over or not. That didn't need to go through an enforcement action.

THE COURT: I was actually one of the attorneys on the *American Airlines vs. D.O.T.* case way back in the day.

MR. MCDONALD: Really?

THE COURT: I was. That involved the expansion of flights from Love Field airport.

What else you got?

MR. MCDONALD: This was also a useful --

THE COURT: And, John, if you have any questions,

pass them up.

MR. MCDONALD: It is also a useful procedure because of the statutory constraints on the agency. As this Court recognized, up to date means up to date. The rulemaking takes time, even if you're using the good cause exception.

And that's especially true in this public health context, where if a drug is in shortage, somebody needs the drug, the agency needs to add that drug to the -- to list in a -- in a brisk manner. And once the shortage is over, it needs to be similarly quick to take it off.

Similarly, importantly, the statute goes out of its way to preserve the confidentiality of the information at issue. And it also addresses a public health circumstance that I don't think we've talked about yet, which is, it gives the Secretary of HHS the discretion to keep the entire thing under wraps at the risk that folks might go and try to horde the drugs. It says, in that instance, HHS Secretary is allowed to keep the entire existence of the shortage secret. How is the agency supposed to have a rulemaking if the entire proceeding is secret?

But even if that -- even if that provision isn't invoked, this -- this kind of controversy is unlike ones cited in plaintiffs' brief. And it doesn't call for the sort of best practices for handling sensitive or confidential information that plaintiffs have cited to. We agree,

administrative agencies consider confidential information all of the time, it's perfectly -- it's perfectly right that they do that.

Here, however, every piece of material information is confidential. If the agency is not allowed to disclose the supply and disclose the demand, how is any member of the public supposed to comment on whether supply is meeting demand?

These are statutory constraints on the agency that, in this case, made a rulemaking impossible. So --

THE COURT: I -- I understand. Honestly, I don't like it. But what I like and don't like doesn't affect what my ruling is going to be.

But I get it. I understand it.

MR. MCDONALD: If I could have one moment, Your Honor.

THE COURT: Yeah.

John, do you have any questions? *(No response)*

(Brief pause)

MR. MCDONALD: Your Honor, I thought of two more things I wanted to --

THE COURT: Go ahead.

MR. MCDONALD: -- leave the Court with.

The Court had asked about the [redacted].

THE COURT: Yeah.

MR. MCDONALD: I wanted to clarify, that Lilly represented to the agency that it was capable of producing that amount as of the time of the representation; not that it was doing so or had done so in the past. And that's the way that the agency considered it.

THE COURT: John, my claw clerk, had reminded me this, this was in my notes that I wanted to ask you about. I think that plaintiffs had a very good point, that the FDA, as well as Eli Lilly, needs to show that there's the capability to store the surplus justifying the decision to take this off the shortage list, and that, obviously, not only that you have the capability to store it -- maybe this is a better question for Eli Lilly, but it would go to FDA, because you should know your record.

And if you-all can't show the ability that Eli Lilly has -- can store this, you can't really make the argument that there's not a shortage anymore. Therefore, the decision would be invalid.

What's the best piece of evidence that you have that you contend FDA was reasonable to rely on Eli Lilly's representation with regards to storage?

And my Eli Lilly counsel, I want you to point that out as well when you come up.

MR. MCDONALD: Your Honor, I think -- I think the best evidence is the -- the charts and the decision memo,

which show not just a large demand, but ability to meet that demand. Which means, there's not a warehouse sitting somewhere full of doses not being touched. Those doses are being moved out of the warehouse at a rapid rate.

THE COURT: The fact that they can -- not necessarily storage, but the fact that they can meet the manufacturing demand -- they can meet the demand via their increased manufacturing capability? Did I say that correctly?

MR. MCDONALD: That's right. And that -- that sort of churn of inventory meant that the manufacturer wasn't shipping out only the newest doses and holding back older doses that might go out -- expire. Of course, like any, you know, rational business, it was sending out the doses of -- the older doses that were still within expiration to be used then.

THE COURT: Okay.

MR. MCDONALD: So --

THE COURT: I get your argument. I just wanted to know if you could point -- point me to somewhere on that.

I had asked the question about the difference in the charts, from [redacted], and the [redacted] And do you have -- you heard Mr. Grossman's --

MR. MCDONALD: I did.

THE COURT: -- contention with that? How do you respond to that?

MR. MCDONALD: I did. I'd only emphasize that ultimately we're talking about, in those [redacted]

And so, when you take data from one table and another table that aren't meant to be compared, there's going to be some -- some difference in how they're reported. And also, we pointed out in our brief that there are going to be doses -- doses that are ordered at the end of one month, but not shipped till the next.

And so, for example, using those timeframes, there are going to be orders in September that are then shipped the beginning of October. So, even assuming it's a fair comparison, you're only seeing the shipments of those orders. And then on the other end, you're going to get orders at the very end of November that aren't shipped until December.

Something that plaintiffs pointed out in their reply was, Well, isn't that a wash? You have some shipments without orders and some orders without shipments. It's not a wash when the demand is going up. You've got fewer orders at the end of October than you did at the end of -- I'm sorry, at the end of September, than you did at the end of November. That's going to be a higher number of orders without shipments.

So, perhaps that's where this [redacted] comes from. But I object to the premise at the outset that these

numbers are fairly comparable to begin with.

THE COURT: Okay.

MR. MCDONALD: So --

THE COURT: I bet a lot of you guys have flights today and I've asked too many questions. I do want to hear from Eli Lilly.

Would you like to wrap up very briefly?

MR. MCDONALD: I would.

One thing I want to leave the Court with is one of the things I started with. At the time of the decision, [redacted] that -- were prepared to react to that demand. And I believe plaintiffs' reply brief referred to the existence of those doses, but I didn't discern any sort of response regarding their significance ever in the briefing. And I think that absence of any response casts a long shadow over the rest of plaintiffs' arguments.

THE COURT: Okay.

MR. MCDONALD: Thanks very much.

THE COURT: Well, let me cast my shadow on to Mr. Hurst -- Ms. Hurst -- what's your name?

MS. MURPHY: Murphy.

THE COURT: Ms. Murphy. I'm so sorry, ma'am. Erin Murphy.

MS. MURPHY: That's correct.

THE COURT: Okay.

MS. MURPHY: No worries at all.

So, thank you for -- for the opportunity to speak on behalf of Lilly. I don't want to rehash a bunch of things that the Government has already covered, so I'm going to try and just stick to, you know, a few specific points, some of the things that Your Honor asked about and a few things that are --

THE COURT: I think if you haven't figured it out, there's a few salient points that I'm sticking on.

MS. MURPHY: Yes.

THE COURT: And Mr. Grossman and Mr. McDonald did a great job, but if you can enlighten me it will be helpful.

MS. MURPHY: Yep. No, and I will --

THE COURT: I think you can probably tell what bothers me.

MS. MURPHY: Yep. And I am happy to talk about a few record-specific things.

I do want to make one overarching point at the outset, which is the nature of the relationship with Lilly's data here and all of that and this accusation we keep seeing from plaintiffs of FDA outsourced this, we just provided whatever we wanted, there was just kind of some of arbitrary one day we'll give you this, one day we'll give you that. That is just not borne out by the record.

If you look at the record, from the very first

submission that we made in the record, at page 290 of the administrative record, the email in which we're providing information to the Government begins with the words, In response to your request. And you see over and over again, when we are providing data and providing it in a different format or some additional data, it's because FDA asked us for it.

So, take, for instance, table five, the wholesaler focus data. That didn't just materialize out of nowhere, one day we said, Oh, we'll give you this. FDA asked us. If you look at -- particularly, there's a bunch of back and forth. There was [redacted], you can find at 422 through 37 of the administrative record and 459 through 92 of the administrative record.

FDA asked us about a dozen questions over the course of a couple of months. Many of which are, Can you also supply this data? We'd like to know what you know about wholesaler inventory. We'd like to know more about what you know about wholesaler inventory. We see that you've given us cumulative on the basis of both drugs, we'd like you to disaggregate it for the two medicines. We'd now like you to disaggregate it by dosage.

They are the ones who are driving what they want from us. And, of course, we are supplying the data. But this

notion that we just kind of gave them whatever we felt like and they never asked any questions, the reason we have different types of data in the record is because FDA wanted different types of data so it could make sure it was looking at this question through all different angles, looking at what's happening right now, [redacted], what does that look reflect in terms of the trends that we've seen over the [redacted]? Does supply look different now than it did in [redacted], when there was a shortage going on? You know, what is -- what has changed, has it changed over time?

Totally reasonable for an agency that's trying to make a present-day and predictive judgment to say, Well, we don't just want to look at what's going on today or what's going on yesterday, we also want to put that in the context of what's been going on [redacted] so we can look at all of that. And I think that really boasts -- gives the lie to this notion that we're driving the process, and really just kind of destroys this argument that there's something arbitrary about the time period here.

FDA's doing what a rational, reasonable agency would do when trying to make predictive judgments; which is, say, We want to look today, and we want to look at today in context to make sure that what we're getting [redacted] is consistent with what we've seen [redacted], is

consistent with the way trends have changed over [redacted].

And as the Government's counsel pointed out, doing the very reasonable thing of saying, Keep giving us data. We went -- and [redacted], so that they always are able to look at it and say, We're not taking your word for it. [redacted] And that is, in fact, what happened.

If you look -- in particular I focus -- you know, you asked about kind of what's -- what's the best evidence in the record? I think a good place to start is table one. That's the focus on the [redacted] stock reports that are showing where this is -- you know, once the FDA does its voluntary remand it says, we are taking another look, we want to make sure we're looking closely at this, [redacted]

Okay, maybe it is the case that sometimes, early in, you know, [redacted]. Let's look at that, let's see what happens over the course [redacted], and see if you're right when you're telling us, you

know, that had to do with a particular day the snapshot was taken and [redacted]. We've [redacted]. They're able to check our work and say, Okay, what you did actually proved out that you are, in fact, producing enough to meet this demand.

So, I think that's a really good place to start. And just to be clear about something that I think plaintiffs have kind of sown some confusion about here, that is absolutely a table that reflects both supply and demand. It is a table that is focused on net inventory balance, net inventory balance is net of demand. It's the balance that's left after we've fulfilled demand and after we've taken into account open orders at the time.

So, it is the number -- it is the supply figure that it bakes in the demand and shows that, yeah, there were a [redacted] But [redacted]. And by the time we get to the [redacted] stock reports and the [redacted] ones, [redacted].

Now, I do think it's important to take that and understand the difference between what's in table one and the cumulative tables two through four. The cumulative ones are a little bit different measure. You have a little bit different

numbers because they're -- not because the cumulative tables aren't using an inventory or supply figure at all.

But because, as we explained when FDA asked us exactly this question, why are these numbers a little bit different, we explained in correspondence, at page 477 of the administrative record, that it's because [redacted]

But as we represented all throughout the proceedings and FDA said in its decision memo, [redacted] Finished product inventory is often going to be a little bit bigger than net inventory balance on a given day, for the reasons we laid out at page 477, that have to do with when you're doing a snapshot of net inventory balance on a particular day, you adjust for open orders, things in transit, a few other dynamics.

That doesn't mean that the cumulative numbers are -- are somehow not a measure of supply or have absolutely nothing to do with inventory. We never said, These have nothing to do with inventory and these don't reflect real numbers of product we have. But there's accounting terminology here and we have to use it accurately. And when we're using one phrase here and one phrase there that's, you know, that's going to be slightly different and you might get a slightly different

number.

And when it happened, FDA didn't just say, Oh, who knows, and throw their hands [redacted]. If you look at that correspondence I referred to earlier, [redacted], that's exactly the type of thing they're asking about.

[redacted]? And we're engaging with them. And all of that, again, goes back to the point of they are not simply just saying, Well, Lilly says there's no shortage, so there must not be a shortage.

They're asking us for more information, they're probing us about anything they identify -- they're probing us about some of the very same things plaintiffs are still talking about today. You can't ignore all of the things that are in the administrative record. The arbitrary and capricious standard does not require the agency to answer any conceivable questions someone might come up with after the fact in its decision memo. It requires it to be based on evidence that's in the record. And there's evidence in the record that shows that these types of questions were answered and dealt with repeatedly throughout the process.

I do want to say a few words about the [redacted].

(Court Reporter interrupts)

MS. MURPHY: But the [redacted] of the capacity representation in [redacted], so, again, as Government counsel said, this was a representation about the capacity that Lilly has. It is not a representation that's wildly off base from what was being produced in months leading up to it. We have months that are [redacted] So, it's not like we've been producing, you know, [redacted] and all of a sudden we're saying tomorrow we'll produce [redacted] It's very --

THE COURT: Slow down just a tad, okay?

MS. MURPHY: Sure.

THE COURT: I'm not going to put you on the rack and stretch you until you slow down or speed up, okay? You're not -- you're not in trouble. You're not -- I want to give you your time.

MS. MURPHY: I'm a Midwesterner and we just kind of talk fast unintentionally.

THE COURT: That's fine. My brain is slow to process.

MS. MURPHY: So -- but, you know, we -- when we were focusing on that figure, its not something that's radically different from what we've been doing in the past. It's pretty close to what had been manufactured.

It is something, also as Government counsel pointed out, [redacted]?

And, in fact, they have found the opposite. That we, [redacted]. And so, they have a [redacted].

And then on top of that, FDA says, We're going to keep monitoring all of this [redacted] going forward. So, if it turns out we're saying we can produce this much and we're radically wrong, and you have some other -- you know, some numbers that don't prove out, they're going to be there to be able to step in. And to this day, we're giving them the data. And if they, you know, reach a point where they have a concern, they'll be able to act on it. But at this point, it's completely reasonable of the agency to say, We have a [redacted].

I would also note that a significant part of the

argument that they're making about the [redacted] comes back to the same flaw that kind of pervades a lot of the arguments they're making; which is, they keep ignoring the surplus that carries over from month to month. So, we don't have to produce all of the supply to meet demand in a given month, because the whole point that we're showing across all these different types of data, and the cumulative in particular, but also the net inventory balances in table one, is that there is [redacted]. So, when you look at supply, you have to think about both supply capacity and existing supply.

Now, that goes to the question Your Honor asked about kind of like the shelf-life question. Now, you know, if you're asking me to somewhere in the record I can show you that says what we have said in our briefs, which is there's a two-year shelf life for these products, I'm not sure there's somewhere that actually, you know, specifically came up of tell us the shelf life. But the representations that we're making when we provide the Government -- the FDA with data here, are not just here's, you know, in the abstract some -- some product we have. It is representations about product that is available to be shipped.

We're not going to count product as available to serve demand if it's not product that's actually able to serve demand. We're not sending out expired products that are not

something that can still be used to serve demand.

So, the FDA, quite reasonably, understood that when we're giving them figures about what we have in inventory that can serve demand, of course we're talking about inventory that's viable inventory that can actually be sent out to serve demand, and we are explaining what carries over in a given month and all of that.

So, again --

THE COURT: One of the big complaints that plaintiff has is that -- it's easy to say, Well, we relied on charts or whatever. But they contend that in this case that not enough was put on the record to -- big 10,000-foot overview versus putting everything that FDA relied on in the decision and listing it or pointing it out in the actual decision that they made in this case.

Do you have a case that says they don't essentially have to put everything and the kitchen sink in for the decision not to be arbitrary and capricious? I'm sure there has to be, that seems like a general proposition of law.

MS. MURPHY: I'm sorry I don't have a case at hand. Because, to me, that's just sort of like the point of the arbitrary and capricious standard is you have to say enough so that people understand what you're doing, but you don't have to answer every conceivable question someone might later look at the evidence and say, Well, what about this, what about

that, what about this, what about that? Especially in the context, as Government counsel reminded, that this is something -- you know, there's a statutory mandate to keep this up to date. You can't sit around writing the decision memo for five months. You've got to take what you got and work with it.

And what they did is entirely reasonable. With each table they explained, here's what this data was, here's what it showed, and here's why that supports our ultimate conclusion. And they explained each type of data supports it for a little bit different reasons.

And that's why, you know, I do think going back to that table one is kind of a really useful way to see how they're showing, you know, if you might be worried about high-level numbers, we've got some low-level numbers, too.

And I also would just take issue with this notion they didn't show a lot of their work here. I mean, they did. They -- they addressed a lot of these issues. A lot of the things that plaintiffs accuse FDA of not addressing, FDA did address in their decision memo. They spent five pages talking about demand for compounded products and the extent to which demand for compounded products would translate into demand for Lilly's drugs. And they ultimately assumed that even though there was evidence that it wouldn't translate, they assumed that most of it would, and said, Even if it would *(sic)*, we're

comfortable about the supply here.

And then on that very same page of the decision memo, when FDA ultimately reaches that conclusion, We feel comfortable about supply, they close out their discussion by saying, We're going to keep request -- we're going to keep monitoring this [redacted] so that if it turns out we were mistaken about just how much demand would increase as the compounding products are taken off the market, we'll be able to see that.

THE COURT: Okay. I know this is a stupid question. I assume that that's continuing to be done at the moment, and FDA continues to stand by their decision as of April the 24th, that there continues to be a surplus rather than a shortage; is that fair to say?

MS. MURPHY: I think that's --

THE COURT: Or my FDA counsel?

MR. MCDONALD: That's accurate, Your Honor.

THE COURT: Okay. All right.

I think I'm good to go.

MS. MURPHY: I just wanted to make sure. I thought there was one other question you might have asked that I wanted to make sure I addressed.

THE COURT: I would like to give Mr. Grossman, since he's taken on two attorneys here, a final chance to say something.

MS. MURPHY: Could I make one last just final point on one thing you had said was bothering you --

THE COURT: Certainly.

MS. MURPHY: -- which is the rulemaking issue.

THE COURT: Yep.

MS. MURPHY: And I would simply say, while I absolutely stand by everything FDA said about why this is not rulemaking. I would also say, it should bother you a little bit less, given that they did, in fact, have notice and opportunity to comment and provide all sorts of material of their own to FDA here.

They could have provided hard data about compounding. They are compounders. They chose not to because they didn't want to share all of their own information about exactly what market they are supplying. So, this is really the last case in which you should be kind of having a lot of sympathy for them, in particular, as the party that's before Your Honor saying they wished they had had more notice and opportunity to participate.

THE COURT: Thank you, ma'am.

Mr. Grossman, I'll give you the last word.

MR. GROSSMAN: Thank you, Your Honor.

There are only three points I wanted to make in response. The first is my friend representing the FDA started off his discussion by reciting the statutory standard that

appears at the very top of the decision about demand exceeding supply over a time period, and then proceeded to talk about all kinds of other things that are in the record that don't actually measure up to those three elements that he started off with.

In that sense, his discussion does match what is in the decision, and so I guess that's consistent at least. But at the same time, I think it only underscores the arbitrariness of what the agency did here, that it sort of -- you can't exactly figure out what metric or standard or approach the agency was taking. It just considered a whole lot of stuff and decided, We kind of know it when we see it. But that's not the standard that my friend began with, and it's not the standard that the statute begins with or that the decision does.

Second, the Court has asked several questions. Everybody has had a chance to answer the question about the [redacted] I think there's a clarification that is needed here. So, that figure comes from a [redacted] Both of my friends represented that that represents Lilly's capacity and not what Lilly is, in fact, doing; that is incorrect.

The letter from Lilly says that Lilly [redacted]

[redacted] This is at plaintiffs' appendix page 116. That -- as I said, that letter was on [redacted] In the month of [redacted] [redacted]. So, that's a little bit less, I would say, than [redacted].

And then third and finally, the Court has asked a number of questions, and I think appropriately so, about the meaning of the aggregate supply data and how that corresponds, if it corresponds in any way, to the inventory that is available to satisfy customer demand. My friend representing the FDA referred to that figure as representing stored surplus. I believe the decision refers to it similarly. Lilly in its briefing has referred to that figure as representing surplus.

But I want to read to you -- this is from plaintiffs' appendix page 122, and this is, again, from the same letter from Lilly. It says, [redacted] [redacted]. And then it goes on to explain all the different things that [redacted]. [redacted] [redacted]

Those are the only points that I wanted to address. Of course, I'm happy to answer any questions the Court might have. Otherwise, we would simply ask the Court to grant the plaintiffs' motion and to deny the others. And to thank the Court for its time today.

THE COURT: If I grant summary judgment on your third claim, does that take care of the case? Do you win on everything?

MR. GROSSMAN: Yes, Your Honor.

We think that the way that the claims have been laid out, if the Court -- that any of them would provide an appropriate basis for vacatur -- for vacatur of the action here. And so, the Court need not address other -- other claims if it doesn't feel the need to reach them.

THE COURT: Okay. I think I don't have any additional questions. I appreciate everyone's arguments here today. And you guys were very diligent, even though I gave you some extra time, I thought you did a great job laying it out very succinctly.

I will say, though, I am not smart enough to make a decision on this until I get the transcript. So, I would like to go and study your arguments more, some of the statements you guys made today, and then went back and tying them to the brief and also the administrative record.

I do not think that I will take long to make a

decision, but, then again, I want to be sure that I do the best job. And as I said, I understand, one way or another, it will go on to the next court, so I want to try to give them as much of my reasoning as possible. And like I said, I'm just trying to do my best here, and I really don't care if I get reversed.

But I do want to see the transcript. But I do understand also that time is of the essence and you-all want a decision. But as soon as we get that transcript -- another thing I would ask from you, I dropped a footnote in the previous decision, I do take it seriously. I don't want to be -- honestly, don't want to be criticized for trying to close public hearings. I really feel strongly about that.

So, you should expect that once Monica is able to give us the transcript that you'll -- if you can get together in three days and give me your proposed redactions, I would like to get it out there. We have had several inquiries, folks that have been calling up here, members of the general public, as well as members of the media that, I'm assuming, did want to attend the hearing today. And I'd like to get the transcript out there as quickly as possible, okay? But we need to did get that to you. And I know Monica will work diligently to do that.

Unless you-all have any more questions for me, I'm prepared to go off the record, okay? No? *(No response)*

(Proceedings Adjourned)

REPORTER'S CERTIFICATE

I, Monica Willenburg Guzman, CSR, RPR, certify that the foregoing is a true and correct transcript from the record of proceedings in the foregoing entitled matter.

I further certify that the transcript fees format comply with those prescribed by the Court and the Judicial Conference of the United States.

Signed this 28th day of April, 2025.

/s/Monica Willenburg Guzman
Monica Willenburg Guzman, CSR, RPR
Texas CSR No. 3386
NCRA No. 32278
Official Court Reporter
The Northern District of Texas
Fort Worth Division

CSR Expires: 7/31/2025

Business Address: 501 W. 10th Street, Room 310
Fort Worth, Texas 76102

Telephone: 817.850.6681

E-Mail Address: mguzman.csr@yahoo.com